UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/933,548	08/20/2001	Christopher William Ogden	NORT 100	6550

23579 7590 04/22/2003

PATREA L. PABST
HOLLAND & KNIGHT LLP
SUITE 2000, ONE ATLANTIC CENTER
1201 WEST PEACHTREE STREET, N.E.
ATLANTA, GA 30309-3400

EXAMINER	
SAKELARIS, SALLY A	

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 04/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/933,548	OGDEN ET AL.	
	Examiner	Art Unit	
	Sally A Sakelaris	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 August 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-38* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Election/Lack of Unity

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions that are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention(as represented by the groups listed below) to which the claims must be restricted.

Group I, claims 1-4, 5-9, and 15-16 are drawn to a method of determining susceptibility, diagnosing prostate cancer and predicting patient outcome through **nucleic acid** analysis.

Group II, claims 1-4, 10, 11, and 13-16 are drawn to a method of determining susceptibility, diagnosing prostate cancer and predicting patient outcome through **protein** analysis.

Group III, claims 1-4, 10-13, 15-16 are drawn to a method of determining susceptibility, diagnosing prostate cancer and predicting patient outcome through **antibody** analysis.

Group IV, claims 17, 18, 21, and 22 are drawn to a method of using a specific agent to determine the level of a **nucleic acid.**

Group V, claims 17, 19, and 20-22 are drawn to a method of using a specific agent to determine the level of a **protein**.

Group VI, claim 23 is drawn to a kit for detecting **nucleic acids**.

Group VII, claim 23 is drawn to a kit for detecting **proteins**.

Group VIII, claims 24-29 and 37 are drawn to a method of treating prostate cancer through nucleic acid administration.

Group IX, Claims 30-35 are drawn to a nucleic acid encoding, genetic construct.

Group X, claim 36 and 38 are drawn to a pharmaceutical composition for treating prostate cancer.

2. The inventions listed as Groups I-X do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

It is noted that the special technical feature of the present claims is a method of determining susceptibility, diagnosing prostate cancer and predicting patient outcome through nucleic acid analysis and as a result, each of the present claims has been presented in improper Markush format, as distinct methods are improperly joined in the claims. With respect to the methods of Groups I and II, each one consists of analysis using an unique nucleic acid or polypeptide respectively, each differing in its structural and functional properties. Additionally, the method claims of Groups I and II are distinct from the other in that both the nucleic acid of group I and the polypeptide of Group II, being analysed in the method, comprise a distinct structure and as a whole each biomolecule is functionally distinct over each other. Each method has a different special technical feature. As the claimed methods use both analysis with polynucleotides and polypeptides, they do not share a special technical feature, nor do the remaining groups(III-X) as distinct methods may not properly be presented in the alternative. Accordingly, the claims have been separated into a number of groups corresponding to the number of different inventions encompassed by the claims, and the claims will be searched only as they read upon the elected invention from the methods of Groups I and II that require different analyses using either polynucleotides, polypeptides or antibodies.

Further, the claimed methods of Groups I-V and VIII have different objectives, require different process steps and require the use of different reagents. The method of Group I requires the steps of determining susceptibility, diagnosing prostate cancer and predicting patient outcome through nucleic acid analysis. The method of Group II requires the steps of determining susceptibility, diagnosing prostate cancer and predicting patient outcome through polypeptide analysis. The method of Group III requires the steps of determining susceptibility, diagnosing prostate cancer and predicting patient outcome through antibody analysis. Group IV involves using a specific agent to determine the level of a nucleic acid while Group V involves using a specific agent to determine the level of a protein. Lastly, the method of Group VIII, involves the steps of treating prostate cancer through nucleic acids administration. Group I is directed to a method utilizing nucleic acids as a reagent, composed of phosphodiester linked nucleotides, Group II is directed to a method utilizing polypeptides as a reagent, composed of peptide bond linked amino acids, while Group III is directed to an entirely different biomolecule as well, antibodies. The nucleic acids, polypeptides, and antibodies of the above methods require different method steps to accommodate their variant physical characteristics. In addition to differences in objectives, effects, and method steps, it is again noted that the method claims of the present Groups are not directed to the detection or identification of molecules having the same or common special technical feature, as they are entirely different biomolecules with different physical structures and therefore different functions and for the reasons discussed above.

The claimed products of Groups VI, VII, IX and X share neither the same special technical feature between each other, but also do not share the same special technical feature

with the methods as explained above. Group VI is directed to a kit for detecting nucleic acids, while Group VII is directed to a kit containing proteins, two very different biomolecules with different structures and functions. Also, Group IX is drawn to nucleic acid genetic construct while Group X is drawn to any pharmaceutical composition, each of these products contains a different special technical feature that defines different inventions between each product and between each of the aforementioned methods as the method may be carried out without the use of the different products of groups VI, VII, IX and X.

3. Applicant is advised that examination will be restricted to only the elected biomolecule (DNA, Protein or Ab): and the election of such should not be construed as a species election. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claims 1-4, 10, 11, 13, 15, 16, 17, 21, 22, and 23. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

FOR EXAMPLE...If applicant elects group I, they will be prosecuting the group's linking claims to the extant that they disclose nucleic acids. Additionally, if applicant elects

group VII, they will further be prosecuting the claim 23 linking claim to the extant that it reads only on the kit comprising an agent capable of detecting a protein etc.

4. Because these inventions are not so linked as to form a single general inventive concept under PCT Rule 13.1, examination of these inventions lacking the same special technical feature would pose a serious burden on the examiner and therefore the lack of unity requirement and subsequent election of desired Group for examination purposes as indicated is proper.

5. Applicant is advised that the reply to this requirement, to be complete, must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communication from the examiner should be directed to Sally Sakelaris whose telephone number is (703) 306-0284. The examiner can normally be reached on Monday-Friday from 8:00AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703)308-1119. The fax number for the Technology Center is (703)305-3014 or (703)305-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to Chantae Dessau whose telephone number is (703)605-1237.

Sally Sakelaris

4/21/2003

GARY BENZION, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600